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Registration Decision RD2014-03

Sodium Lauryl Sulfate

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Registration Decision for Sodium Lauryl Sulfate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Stepanol DX (AS165) N and MTDX-CR, containing the technical grade active ingredient sodium lauryl sulfate, to kill German cockroach adults and nymphs in and around buildings.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-16, *Sodium Lauryl Sulfate*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for sodium lauryl sulfate and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-16. This decision is consistent with the proposed registration decision stated in PRD2013-16.

For more details on the information presented in this Registration Decision, please refer to PRD2013-16, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Sodium Lauryl Sulfate?

Sodium lauryl sulfate, the technical grade active ingredient in the technical product Stepanol DX (AS165) N, is a sodium salt of a long hydrocarbon chain linked to sulfate. Formulated as the end-use product MTDX-CR and used in and around buildings, it kills German cockroach nymphs and adults on contact.

Health Considerations

Can Approved Uses of Sodium Lauryl Sulfate Affect Human Health?

MTDX-CR containing sodium lauryl sulfate is unlikely to affect human health when used according to label directions.

Exposure to sodium lauryl sulfate may occur when applying the end-use product, MTDX-CR, or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient sodium lauryl sulfate is expected to be slightly acutely toxic by the oral route, moderately acutely toxic by the dermal route, severely irritating to the skin, eyes, and respiratory tract, and is not a skin sensitizer.

Exposure to humans from the commercial use of MTDX-CR is not expected to be of concern due to the precautionary statements present on the end-use product label that are aimed at mitigating exposure.

Residues in Food and Water

Dietary risks from sodium lauryl sulfate on food and water are not of concern.

MTDX-CR is not for direct application to food. Also, the end-use product label has precautionary statements not to contaminate food, feed, and water with the end-use product; therefore, dietary exposure to sodium lauryl sulfate from the proposed end-use product use is anticipated to be negligible.

No risk due to exposure from drinking water is anticipated as sodium lauryl sulfate is unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Risks from Handling MTDX-CR

Risks are not of concern when MTDX-CR containing sodium lauryl sulfate is used according to label directions, which include precautionary statements.

MTDX-CR is to be applied by commercial applicators inside and outside buildings.

Occupational exposure is of concern during handling, loading and mixing of MTDX-CR and clean-up activities when workers are exposed to the concentrated form (98% w/w); however, risks from exposure are not anticipated when workers follow label directions that include exposure mitigation measures, such as personal protective equipment, cautionary, hygiene, and restricted-entry statements on the end-use product label.

Environmental Considerations

What Happens When Sodium Lauryl Sulfate Is Introduced Into the Environment?

The insecticide, MTDX-CR, is proposed to be applied in and around buildings to kill German cockroaches (*Blatta germanica*). As the application method is a handheld sprayer pump, and the product is applied directly to the target pest, the exposure to non-target organisms is expected to be negligible. The risk to the environment is not expected to be a concern.

Value Considerations

What Is the Value of MTDX-CR?

MTDX-CR is a non-conventional product that kills German cockroach nymphs and adults on contact, in and around buildings. German cockroaches can be pests in these areas. MTDX-CR is applied directly on German cockroaches. The active ingredient, sodium lauryl sulfate, is a new mode of action for use against cockroaches.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MTDX-CR to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "WARNING – POISON," "DANGER – SKIN IRRITANT," and "DANGER – EYE IRRITANT" are required on the principal display panels of the labels of Stepanol DX (AS165) N and MTDX-CR.

Standard hazard and precautionary statements are also required on both the labels to inform workers of the irritation potential of the active ingredient and to caution that it is harmful when swallowed, inhaled or absorbed through the skin.

Based on the hazard profile (for example, likelihood to irritate the respiratory tract and oral mucosa), standard personal protective equipment are required for mixers and loaders (for example, long clothing, shoes and socks, waterproof gloves, protective eyewear, and respirator.)

A precautionary statement on the end-use product label indicating that the handling, loading/mixing of the end-use product, as well as the clean-up and maintenance activities, must be performed in a well-ventilated area is required.

Label statements advising individuals not to allow contact of the products with skin, eyes or clothing and to avoid breathing dust or spray mist are required.

To protect bystanders, label statements are required to instruct that the product must not be applied in a way that it will contact workers or other persons, either directly or through drift, and indoor application of the end-use product in commercial facilities is restricted to vacant areas only.

To protect from postapplication exposure, a label statement is required to restrict entry/re-entry into treated areas until the spray is dried and the areas are thoroughly ventilated.

The end-use product label instructs that workers not contaminate food or feed, and cover food contact surfaces and equipment during treatment or, alternatively clean them thoroughly before reuse.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-16) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.